Continuation Guidance – Budget Year Four
Attachment C
Focus Area C: Laboratory Capacity—Biologic Agents

Background

The goal of Focus Area C is to expand biological laboratory capacity in all jurisdictions to identify and respond to bioterrorism incidents, other outbreaks of infectious disease, and other public health threats and emergencies. Focus Area C funding will allow a consortium of public health, hospital-based, food testing, veterinary, and environmental testing laboratories to participate in the Laboratory Response Network (LRN).

The LRN is a consortium of laboratories that provides immediate and sustained laboratory testing and communication in the event of public health emergencies, particularly in response to acts of bioterrorism. The LRN is comprised primarily of state, local, and Federal public health laboratories. An optimum number of registered, participating LRN laboratories throughout the U.S. is determined by the LRN working group. Preliminary testing and screening is performed primarily in a distributed instead of a centralized fashion to ensure a prompt initial response; a system of triage and referral of specimens ensures transfer of appropriate materials to specialty laboratories, where sophisticated equipment and expertise is applied to analyze a specimen.

The goals of the LRN are to:

1) Ensure that the nation's public health, clinical, and other select laboratories are prepared to detect and respond to a bioterrorism or chemical terrorism event in an appropriate and integrated manner.
2) Ensure that all member reference laboratories collectively maintain state-of-the-art biodetection and diagnostic capabilities and surge capacity as well as secure electronic communication of test results for the biological and chemical agents likely to be used in a crime.
3) Work with other Departments and Agencies to ensure a successful Federal response to an act of bioterror and to facilitate and optimize the ability of States to competently respond independently to biocrimes or public health emergencies in the State.
4) Promote CDC and HHS' bioterrorism research agenda and CDC's internal response needs.

Examples of specific accomplishments of the LRN include:

- A registry and linkage of clinical and private laboratories in the U.S. that includes sentinel laboratories and reference laboratories;
- Complete, accurate, and standardized protocols for all levels of testing for agents deemed critical; a secure but easily accessible supply of standardized reagents and controls produced either by CDC or by commercial manufacturers;
- Secure electronic laboratory reporting that integrates with key epidemiologic, surveillance, and emergency response components; and
- Training and proficiency testing necessary to accomplish any level of testing or response.

CRITICAL CAPACITY #8: To develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

RECIPIENT ACTIVITIES:

1. Develop and maintain the capability of Level A (sentinel) laboratories to (a) perform rule-out testing on critical BT agents, (b) safely package and handle specimens, and (c) refer to LRN Level B/C (reference/confirmatory) laboratories for further testing. **(LINK WITH FOCUS AREAS D AND G AND HRSA PRIORITY AREA #4)**

2. **CRITICAL BENCHMARK #12:** Complete and implement an integrated response plan that directs how public health, hospital-based, food testing, veterinary, and environmental testing laboratories will respond to a bioterrorism incident, to include: (a) roles and responsibilities; (b) inter- and intrajurisdictional surge capacity; (c) how the plan integrates with other department-wide emergency response efforts; (d) protocols for safe transport of specimens by air and ground; and (e) how lab results will be reported and shared with local public health and law enforcement agencies, ideally through electronic means. **(LINK WITH FOCUS AREAS A, B, D, E AND F, and CROSS CUTTING ACTIVITY *LABORATORY CONNECTIVITY*, Attachment X)**

3. In accord with Critical Benchmark #12, address the identified needs for testing food specimens for critical BT pathogens. This may be done by contracting for services with laboratories that possess the requisite capabilities, by sponsoring such capability development within collaborating organizations (such as food regulatory laboratories), and/or by developing the requisite capabilities directly within public health department laboratories. Technical assistance with respect to selection of analytic methods is available through FDA, in consultation with CDC (see Appendix 1 for FDA contact information).

4. Establish and maintain operational relationships with local members of HazMat teams, first responders, local law enforcement and FBI to provide laboratory support for their response to bioterrorism, including environmental testing for exposure assessment and chain-of-custody procedures. Examples of enhanced these relationships include designated points of contact, cross-training in each discipline, and/or joint sponsorship of conferences. **(LINK WITH FOCUS AREA D)**

5. Enhance relationships with hospital-based laboratory practitioners, university laboratories, and infectious disease physicians through participation in infectious disease rounds and conferences. **(LINK WITH FOCUS AREA D)**

(Smallpox) Appoint a liaison from the state or local LRN-member laboratory to participate in meetings and conference calls with smallpox steering committee, stakeholders, and any other activities relevant to LRN operations and smallpox activities.

CRITICAL CAPACITY #9: As a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.

RECIPIENT ACTIVITIES:

1. Continue to develop or enhance operational plans and protocols that include: (a) specimen/samples transport and handling; (b) worker safety; (c) appropriate Biosafety Level (BSL) working conditions for each threat agent; (d) staffing and training of personnel; (e) quality control and assurance; (f) adherence to laboratory methods and protocols; (g) proficiency testing to include routine practicing of LRN validated assays as well as participation in the LRN's proficiency testing program electronically through the LRN website; (h) threat assessment in collaboration with local law enforcement and FBI to include screening for radiological, explosive and chemical risk of specimens; (i) intake and testing prioritization; (j) secure storage of critical agents; and (k) appropriate levels of supplies and equipment needed to respond to bioterrorism events with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident. **(LINK WITH FOCUS AREA D)**

2. **CRITICAL BENCHMARK #13:** Ensure capacity exists for LRN validated testing for all Category A agents and other Level B/ C protocols as they are approved.

3. Ensure at least one public health laboratory in your jurisdiction has the appropriate instrumentation and appropriately trained staff to perform CDC-developed real-time polymerase chain reaction (PCR) and time-resolved fluorescence (TRF) rapid assays. Integrate new advanced rapid identification methods approved by the LRN into the current laboratory-testing algorithm for human, environmental, animal or food specimens. Contact CDC technical support staff for further information on approved equipment as necessary. **(LINK WITH FOCUS AREA B)**

4. **CRITICAL BENCHMARK #14:** Conduct at least one simulation exercise per year, involving at least one threat agent in Category A, that specifically tests laboratory readiness and capability to perform from specimen threat assessment, intake prioritization, testing, confirmation, and results reporting using the LRN website. **(MAY LINK WITH ALL FOCUS AREAS)**

5. Ensure the availability of at least one operational Biosafety Level 3 (BSL-3) facility in your jurisdiction. If not immediately possible, BSL-3 practices, as outlined in the CDC-

NIH publication "Biosafety in Microbiological and Biomedical Laboratories, 4th Edition" (BMBL), should be used (see www.cdc.gov/od/ohs) or formal arrangements (i.e., MOU) should be established with a neighboring jurisdiction to provide this capacity.

6. Ensure that laboratory registration, operations, safety, and security are consistent, at a minimum with the requirements set forth in Select Agent Regulation (42 CFR 73) "Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule" and any subsequent updates as detailed in www.cdc.gov/od/sap and www.aphis.usda.gov/vs/ncie/bta.html. Pursuant to 18 USC section 175b, as added by section 817 of the USA PATRIOT Act of 2001, P.L. 107-56, aliens (other than aliens lawfully admitted to the United States for permanent residence) are prohibited from possessing select agents if they are nationals of countries as to which the Secretary of State (pursuant to provisions of the Export Administration Act of 1979, the Foreign Assistance Act of 1981, or the Arms Export Control Act) has made an unrevoked determination that such countries have repeatedly provided support for acts of international terrorism. **(LINK WITH FOCUS AREA D)**

7. Enhance electronic communications and LRN electronic laboratory reporting, at the bench level, to enable integration with CDC's LRN capacity monitoring efforts, online results reporting, sentinel surveillance, proficiency testing, multi-center validation studies, and support for future LRN site enhancements. Laboratories should participate in reporting results of LRN proficiency testing electronically, as they would in an actual event. Laboratories should have appropriate computer equipment, firewall and high-speed Internet connectivity to access the LRN's protocols, reagents, and lab user applications. **(LINK WITH FOCUS AREA D, E AND CROSS CUTTING ACTIVITY *LABORATORY DATA STANDARD,* Attachment X)**

8. (Smallpox) Identify the laboratories that have the capacity for LRN-validated testing and reporting of *Variola major, Vaccinia and Varicella* through human and environmental samples. Each state should have at least one laboratory that can meet CDC biosafety and security requirements for variola-specific testing.